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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,845	10/23/2003	John F. Connolly	85202-102 ADB	5384

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EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/690,845	CONNOLLY ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-12,15 and 16* is/are rejected.

7)☒ Claim(s) *2,3,13 and 14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

Claims 1-3, 5-7, 9, 10, and 12-16 are objected to because of the following informalities:

On line 5 of claim 1, "simultaneously with the presentation of the test," should be replaced with "simultaneously presenting the neuropsychological test to the patient and"

Also on line 5 of claim 1, "a patient's" should be replaced with "the patient's";

On line 6 of claim 1, "activity using" should be replaced with "signals using";

On line 7 of claim 1, "bandpass settings" should be replaced with "bandpass filter settings";

Also on line 7 of claim 1, "recording late-occurring" should be replaced with "recording of late-occurring";

On line 8 of claim 1, "a subject's" should be replaced with "the patient's";

On line 15 of claim 1, "the standardized" should be replaced with "the neuropsychological";

On line 17 of claim 1, "prognoses" should be replaced with "a prognosis";

On line 18 of claim 1, "tests" should be replaced with "test";

On line 1 of claim 2, "above steps" should be replaced with "steps of the method";

On line 4 of claim 2, "the typical" should be replaced with "a typical";

On lines 1-2 of claim 3, "above steps" should be replaced with "steps of the method";

On line 3 of claim 5, "the neuropsychological test scores" should be replaced with "test scores of the neuropsychological test";

On line 2 of claim 4, "this association" should be replaced with "an association between the ERP data and the obtained behavioral data".

On line 2 of claim 6, "the N400" should be replaced with "the N400 component of the ERP";

On lines 2-3 of claim 7, "the P300 and the LPC (late positive component)" should be replaced with "the P300 component and the LPC (late positive component) of the ERP";

On lines 3-4 of claim 9, "the two averaged waveforms (congruent and incongruent)" should be replaced with "the two waveforms, wherein one waveform is congruent and the other is incongruent";

On line 2 of claim 10, "the three levels of difficulty" should be replaced with "three levels of difficulty of the neuropsychological test";

On lines 2-3 of claim 10, "the three electrode sites (Fz, Cz, and Pz)" should be replaced with "three electrode sites, the three sites being Fz, Cz, and Pz";

On line 2 of claim 12, "the sum" should be replaced with "a sum";

On line 1 of claim 13, "using the" should be replaced with "wherein the neuropsychological test comprises the";

On line 2 of claim 13, "the computerized PPVT" should be replaced with "a computerized Peabody Picture Vocabulary Test (PPVT)";

On line 2 of claim 14, "PPVT-R" should be replaced with "Peabody Picture Vocabulary Test—Revised (PPVT-R)"

On line 3 of claim 14, "is used" should be replaced with "are used"

On lines 1-2 of claim 15, "the correlational analysis" should be replaced with "the analysis relating ERP data to obtained behavioral data";

On line 1 of claim 16, "the features" should be replaced with "features";

On line 2 of claim 16, "the highest correlation" should be replaced with "the highest correlation between the ERP data and the obtained behavioral data"

On line 3 of claim 16, "i.e.," should be replaced with "i.e."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-12, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-9 recite the limitation "the analysis" on line 1 of claim 4, on line 1 of claim 5, on line 2 of claim 6, on line 2 of claim 7, on line 1 of claim 8, and on line 1 of

claim 9. However, neither the claims themselves nor claim 1, upon which each of claims 3-9 depends, recites a limitation corresponding to "the analysis". However, in claim 1, the method includes the separate steps of "applying a series of analysis algorithms that relate ERP data to obtained behavioral data in an interpretable manner" and of "applying a series of analysis algorithms that permit interpretation of ERP with in the context of the standardized test's framework even in the absence of behavioral data". It is assumed that "the analysis" refers to at least one of these steps of applying a series of analysis algorithms, but it is still unclear as to whether "the analysis" refers to a particular one of the distinct steps of analysis or both. For the purposes of this examination only, "the analysis" is interpreted as referring to either of the two steps of applying a series of analysis algorithms. However, the applicant must, in any case, change the claim language to clarify what is meant by "the analysis".

Claim 12 recites "the method provides for the analysis: one baseline case in which the sum is composed of a single t-score (at the peak); and ten different semi-intervals varying by 20 ms from 20 ms to 200 ms." However, the meaning of this claim language is unclear. In particular, the notation "provides for the analysis:" is unclear since the language following the colon fail to describe steps of an analysis. Also, it is unclear how "the sum" can be composed of one value, when a sum is defined as the result of two values added together. Therefore, the language fails to convey any limitations on the steps of applying analysis algorithms in claim 1, upon which claim 12 depends. For purposes of this examination only, the claim is being interpreted to mean that one of the steps of applying a series of analysis algorithms involves analyzing one

baseline case in which some value is composed of a single t-score and analyzing ten different semi-intervals of the ERP data and the behavioral data, where the semi-intervals comprise 20 ms segments of the signal from 20 ms to 200 ms. However, the applicants must still amend the claim language to clarify the meaning of the claim

Claim 15 recites the limitations "these optimal waveform features" on line 2 of claim and "the magnitude tends to one" on line 3 of the claim. While "these optimal waveform features" admit that particular waveform features are required, it is unclear as to what those particular features are. Furthermore, it is unclear which magnitude tends to one. As a result of these problems, the claim lacks any clear meaning and is impossible to interpret. For the purposes of this examination only, the phrase "these optimal waveform features" are being interpreted to mean any waveform features, and "the magnitude tends to one" is also interpreted as any situation in which the correlation is optimized. However, the applicants must still amend the claim language to clarify the meaning of these limitations in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 7, 15 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,434,419 to Gevins et al. (herein referred to as Gevins '419). Gevins '419discloses a method for cognitive function assessment in a patient (col. 2, lines 25-29 of Gevins '419), wherein a neuropsychological test is adapted to a computer format to present stimuli to the patient (col. 8, lines 21-26; col. 9, lines 5-17 of Gevins '419). The test was simultaneously presented to the patient while recording the patient's EEG signals using standard research level EEG equipment, including particular bandpass filter settings that enable recording of late-occurring cognitive ERPs from a number of locations on the patient's head (col. 8, lines 2-17; col. 9, lines 8-13; col. 10, line 66-col. 11, line 3 of Gevins '419). The recorded EEG signals were manipulated in order to examine each sample of recorded EEG and average together (col. 11, lines 6-10 of Gevins '419). A series of analysis algorithms were applied that relate ERP data to obtained behavioral data in an interpretable manner (col. 1, lines 42-56; col. 11, line 25- col. 12, line 56 of Gevins '419), and a series of analysis algorithms were applied that permit interpretation of ERP within the context of the neuropsychological test's framework even in the absence of behavioral data (col. 12, line 42-col. 14, line 13; col. 14, lines 14-44 of Gevins '419). Prognosis of patient outcome was made using ERP data obtained using the computer-adapted neuropsychological test (col. 14, lines 20-27; col. 25, lines 18-26; col. 25, lines 30-50; col. 26, lines 60-65 Gevins '419).

Regarding claim 5, the analysis uses waveform features and parameters that maximize the correlation between the ERP components and the neuropsychological test scores (col. 12, lines 48-56; figs. 4, 5, 6 of Gevins '419).

Regarding claim 7, the function assessed is that of memory ability (col. 9, lines 10-12 of Gevins '419) and the analysis uses the P300 component of the ERP (col. 11, lines 8-10; col. 12, line 50-col. 13, line 22 of Gevins '419), wherein the P300 component of the ERP is a late positive component LPC (see paragraph 0246 of US Patent Application Publication 2003/0013981 to Gevins et al.; col. 8, lines 47-50 of US Patent No. 5,363,858 to Farwell; col. 4, line 57-col. 5, line 17 of US Patent No. 5,243,517 to Schmidt et al.)

Regarding claim 15, the analysis relating the ERP data and the behavioral data is adjusted to fit some waveform features, wherein, by doing so, the correlation is optimized, wherein the correlation is optimized by making the correlation as effective as possible at the time of invention (col. 8, lines 50-53; col. 12, line 43-col. 13, line 22 of Gevins '419).

With regard to the language of claim 16, the applicants should note that this is merely "results" language, which cannot be relied upon to define over the prior art of Gevins '419, since the reference teaches all of the claimed steps and their recited relationships. Moreover, the examiner will presume that the recited results are inherent in Gevins '419, since all the claimed steps and the relationships therebetween are met by the reference. If the recited result is not inherent in Gevins '419, then this would mean that the applicants have failed to recite one or more critical features of the present

invention (i.e. a problem under 35 U.S.C. 112, 1st paragraph). See Ex parte Masham 2 USPQ 2nd 1647.

Allowable Subject Matter

Claims 2, 3, 13, and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 4-6, and 8-11 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 2, the prior art of record fails to teach or fairly suggest a method for cognitive function assessment in a patient wherein a series of analysis algorithms are applied to relate event related potentials (ERP) data to obtained behavioral data in an interpretable manner, and wherein the steps of the method are conducted in such a manner as to permit the evaluation of a patient's state of mental functioning using ERP even if the patient is unable to verbally or behaviorally perform the test in the typical fashion.

Regarding claim 3, the prior art of record fails to teach or fairly suggest a method for cognitive function assessment in a patient wherein the steps of the method are used to evaluate patient progress through medical treatment using event-related potential data obtained using the computer-adapted neuropsychological tests. US Patent

Application Publication No. 2003/0013981 to Gevins et al (herein referred to as Gevins '981) discloses a method in which patient progress through medical treatment is evaluated using ERP data obtained by a computer-adapted neuropsychological test (see paragraphs 0017, 0021, 0022, 0079, 0080, 0082-0094, 001014-0143, 0173-0201, 0218-0251 of Gevins '981). However, Gevins '981 fails to apply a series of analysis algorithms that permit interpretation of ERP data within the context of the neuropsychological test's framework even in the absence of behavioral data. Instead, Gevins '981 continually relies upon both ERP data and behavioral data to make a prognosis of patient outcome.

Regarding claim 4, the prior art of record fails to teach or fairly suggest a method for cognitive function assessment in a patient wherein the series of analysis algorithms applied to relate event-related potential (ERP) data to obtained behavioral data in an interpretable manner use the Pearson correlation coefficient to evaluate the strength of the association.

Regarding claim 6, the prior art of record fails to teach or fairly suggest a method for assessment of semantic comprehension ability in a patient wherein the wherein the series of analysis algorithms applied to relate event-related potential (ERP) data to obtained behavioral data in an interpretable manner wherein the analysis uses the N400 component of the ERP.

Regarding claims 8-11, the prior art of record fails to teach or fairly suggest a method for cognitive function assessment in a patient wherein the wherein the series of analysis algorithms applied to relate event-related potential (ERP) data to obtained

behavioral data in an interpretable manner uses a discrimination formally expressed using serial t-scores that provide a statistical method of comparing two waveforms on a point-by-point basis to establish where the waveforms differed in time.

Regarding claim 12, the prior art of record fails to teach or fairly suggest a method for cognitive function assessment in a patient wherein a series of analysis algorithms are applied that relate ERP data to obtained behavioral data in an interpretable manner and that permit interpretation of ERP within the context of the neuropsychological test's framework even in the absence of behavioral data, wherein at least some part of the analysis algorithms comprise analyzing one baseline case in which some value is composed of a single t-score and analyzing ten different semi-intervals of the ERP data and the behavioral data, where the semi-intervals comprise 20 ms segments of data of the signal from 20 ms to 200 ms.

Regarding claim 13, the prior art of record fails to teach or fairly suggest a method for cognitive function assessment in a patient using the first level of the computerized PPVT in conjunction with a centro-parietal montage (Cz and Pz).

Regarding claim 14, the prior art of record fails to teach or fairly suggest a method for cognitive function assessment in a patient wherein correlation coefficients, which numerically express a relationship linking certain elements of the event-related potentials (ERP) to Peabody Picture Vocabulary Test-Revised (PPVT-R) scores", are used to elucidate which waveform features are critical.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 4,932,416 to Rosenfeld

US Patent No. 6,754,524 to Johnson, Jr.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Patricia Mallari
Patent Examiner
Art Uni 3736

/Robert L. Nasser/
ROBERT L. NASSER
PRIMARY EXAMINER